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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,319	07/15/2005	Philippe A. Tessier	6013-149us	3470

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EXAMINER	
TSAY, MARSHA M	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 04/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/517,319	TESSIER ET AL.	
	Examiner	Art Unit	
	Marsha M. Tsay	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-13 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-13 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-13 are pending and currently under examination.

Priority: The benefit date is July 5, 2003, for the purpose of prior art.

Specification

The disclosure is objected to because of the following informalities: the priority data needs to be updated.

Appropriate correction is required.

Claim Objections

Claims 3, 10, 12 are objected to because of the following informalities: in claim 3, the term "cell recruitement" should be corrected to "cell recruitment"; in claim 10, the terms "sens or an anti-sens mRNA" should be corrected to "sense or an anti-sense mRNA"; in claim 12, the term "therapeutically affective amount" should be corrected to "therapeutically effective amount". Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 13 provides for the use of a S100 protein, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process

applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 13 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1 and 9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods and compositions of an antibody binding to S100 protein, does not reasonably provide enablement for a fragment of the antibody to bind to S100 protein. The specification does not enable any person skilled in the art

to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The scope of the instant claims is not commensurate with the enablement of the instant disclosure, because practice of the claimed invention would require undue experimentation by an artisan of ordinary skill in the art to ascertain which fragments of the S100 antibody function in the same way as the wild-type antibody. Thus there could be thousands of fragments which contain substitutions, deletions, additions etc. Thus for the instant claimed invention, it would require an undue burden of experimentation for a skilled artisan to determine exactly which fragments were active.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state

of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

In the instant case the quantity of experimentation would be large since there are myriad substitutions, deletions or insertions to choose from. The amount of guidance in the specification is zero with regard to which amino acids in the S100 antibody are essential for binding to S100 protein. No working examples are present of fragments of antibodies binding to S100 protein. The nature of the invention is such that many different antibodies may or may not bind to S100 protein. The state of the prior art is that even antibodies that are 99.99% similar to the wild-type antibody are at times not fully active. The relative level of skill in this art is very high. The predictability as to what substantially similar protein will have which activity is zero.

When the factors are considered in their entirety, the Wands analysis dictates a finding of undue experimentation and thus, the claims are not enabled.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites an effective amount of chemotactic factor inhibitor. The claim is indefinite because neither the claim nor the specification define quantitatively what constitutes an effective amount of inhibitor. There is also no indication in the claim as to

for what the amount is to be effective. Also, the claim recites a protein of the MRP family. The claim should define what MRP is. Also, "administrating" should read "administering".

Claim 2 recites said modulation totally or partially inhibits said inflammatory reaction or totally or partially increases said inflammatory reaction. The claim is indefinite because of the terms "totally" or "partially". It is unclear how the inflammatory reaction can be partially inhibited versus totally inhibited or partially increased versus totally increased.

Claims 3-7 and 11 are included in this rejection because they are dependent on claim 1 and do not cure the defect.

Claim 8 recites an effective amount. The claim is indefinite because neither the claim nor the specification define quantitatively what constitutes an effective amount of inhibitor. There is also no indication in the claim as to for what the amount is to be effective. Also, it is unclear if a different effective amount is needed to inhibit or activate an inflammatory reaction.

Claims 9 and 10 are indefinite because they do not further limit the claim.

Claim 10 recites an inhibitor of activity acquisition of said chemotactic factor. It is unclear what an inhibitor of activity acquisition of said chemotactic factor is.

Claim 12 recites a therapeutically affective [sic] amount of a chemotactic factor inhibitor. The claim is indefinite because neither the claim nor the specification define quantitatively what constitutes a therapeutically effective amount of inhibitor. There is

also no indication in the claim as to for what the amount is to be effective. Also, the claim should define what "MRP" is.

Claim 13 provide for the use of a S100 protein, but since the claim does not set forth any steps involved in the method/process, it is unclear what method/process Applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. Also, the claim should define what "MRP" is.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Geczy et al. (US 5731166). Geczy et al. teach the chemotactic protein CP-10 can be used to alter the inflammatory capacity of mammals (col. 4 lines 50-65). It is known in the art that CP-10 is murine S100A8 protein (see Rouleau et al. reference). In example 1, step 3, Geczy et al. teach the isolation and purification of CP10 (col. 9 line 65; claims 12-13). In example 2, purified CP-10 and CP-$10_{42\text{-}55}$ were injected subcutaneously into Sprague-Dawley rats (col. 16 line 15; claims 1-8, 11). Geczy et al. also specifically teach a method for modulating an inflammatory response in a mammal comprising the step of administering CP-10 protein or a fragment of CP-10 protein (col. 36 lines 15-45;

claims 1-8, 11), wherein the inflammatory response is from arthritis, sarcoidosis, and so forth (col. 4, lines 48-60; claim 3) and the inflammatory reaction involves T-cells (col. 4 lines 48-50; claim 4). Furthermore, Geczy et al. teach CP-10 analogues, mutants, fragments, homo- and heter-dimers of CP-10, as well as to antibodies reacting with CP-10 and antagonists of CP-10 (col. 5-6 lines 10, 35, 45-55; claims 9-10).

Claims 1-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Hillman et al. (US 6103497). Hillman et al. teach two human S100 proteins, S100P1 and S100P2, and their use for treating disorders (col. 1, lines 8-10). In examples IX-X, Hillman et al. teach the expression and purification of S100P (col. 37-38, lines 40-65; claims 12-13). Hillman et al. further teach the production of S100P specific antibodies wherein purified S100P is used to immunize rabbits (col. 38, lines 3-7; claims 1, 6-11). The pharmaceutical composition comprising S100P can be administered to treat disorders such as rheumatoid arthritis, gout, leukemia, and so forth (col. 20-21, lines 40-67; claims 1-4). The pharmaceutical composition can be administered orally, intravenously, subcutaneously, intranasally (col. 24, lines 36-40; claim 5). Hillman et al. also teach sense and anti-sense RNA molecules can be prepared and administered as a chemotactic inhibitor (col. 23, lines 11-65; claim 10).

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is 571-272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

April 17, 2006

ROBERT A. WAX
PRIMARY EXAMINER